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(54) Title: SURGICAL IMPLANT

(57) **Abstract:** A surgical implant suitable for treatment of hernias is provided. The implant comprises a mesh having a residual maximum mass density of $50g/m^2$. The mesh comprises strands forming spaces and the strands comprise filaments forming pores. The spaces and pores are sized to minimise foreign body mass for implantation and to encourage integration of the implant. The mesh may be delivered using Dual Phase Technology™ for ease of handling, cutting and placement. The Dual Phase Technology™ may include encapsulation or coating with hydrogel.

"Surgical Implant"

The present invention relates to the treatment of a hernia such as a uterovaginal prolapse and, in particular, to a surgical implant for use in such treatment and to a related surgical procedure and device.

A hernia is basically a defect resulting in the protrusion of part of an organ through the wall of a bodily cavity within which it is normally contained. For example, a fairly common and well known type of hernia is a defect in the lower abdominal wall resulting in a sac which may contain a portion of the intestine protruding through the abdominal wall. This is referred to as an inguinal hernia. Similarly, a defect in the abdominal wall after surgery is referred to as an incisional hernia. Another type of hernia is a defect in the pelvic floor or other supporting structures resulting in a portion of the uterus, bladder, bowel or other surrounding tissue protruding through, e.g., the

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vaginal wall. This is usually referred to as uterovaginal prolapse.

A common way of treating hernias is to repair the defect by sutures, whether or not the hernial sac is also sutured or repaired, in order that the protruding organ is contained in its normal position. As the defect generally comprises a weakening and attenuation leading to parting of tissues in a fascial wall, it is usually necessary to apply tension to the sutures in order to close the parted tissues. Thus, the fascial wall is generally pinched or tensioned around the area of the defect in order to close the parted tissues.

This treatment is generally effective, but does have some inherent problems. In particular, the pinching or tensioning of tissue around the defect can lead to discomfort and/or recurrence of the hernia. Additionally, in the case of uterovaginal prolapse, such pinching or tensioning of the vaginal wall almost inevitably results in anatomical distortion (such as narrowing of the vaginal cavity) with consequential pain and quality of life implications for the patient and relatively high recurrence and/or complication rates.

In order to address these problems, in the case of inguinal hernia repair, it has been suggested to make use of a surgical implant to overlay or close the weakened and parted tissues without the need to pinch or tension the surrounding tissue of the

fascia. Such surgical implants generally comprise meshes and are now widely used in inguinal hernia repair. Meshes may be applied subcutaneously (i.e. under the skin), internally or externally of the abdominal wall and may be either absorbable or non-absorbable depending on the nature and severity of the particular defect being treated. Meshes may be applied in combination with sutures to hold the mesh in place or, alternatively, with sutures that close the parted tissues as in a "non-mesh" technique. Meshes are usually applied in open surgical procedures, although they may sometimes be applied in laparoscopic surgical procedures.

A typical mesh for an inguinal hernia repair comprises woven or knitted polypropylene such as Marlex® or Prolene®. Such meshes have a number of desirable properties that make them effective for use in hernia repair. For example, they are made of materials that are suitably inert so as to be less likely to cause adverse reactions when implanted in the body. Furthermore, they are mechanically strong, cheap, easily sterilisable and easy to work with.

However, conventional meshes have a number of inherent problems. For example, fistula or sinus (i.e. abnormal passages between internal organs or between an internal organ and the body surface) can develop as a result of a mesh being implanted and left inside the body. More generally, the placement of a foreign body subcutaneously can also lead to

inflammation or infection. Similarly, edge extrusion (i.e. the erosion of body tissue around the edge of the mesh) can occur. Nevertheless, overall, the use of meshes is generally considered to be beneficial in the treatment of incisional and inguinal hernias.

It has also been suggested to use meshes in the treatment of uterovaginal prolapse. Meshes that have been proposed for use in the repair of uterovaginal prolapse are similar to those that are used for the repair of inguinal hernia and such like. However, there is concern that the above mentioned problems with the use of meshes are greater when a mesh is placed in the vaginal wall as this tissue is generally thin only just below the surface and therefore more prone to adverse reactions. Furthermore, the placement of a foreign body close to the rectum and urinary tract may increase the risk of infection, inflammation, erosion, fistula or translocation. Thus, it is a relatively widespread view that the use of meshes in the treatment of vaginal prolapse is less desirable than in the treatment of other hernias.

Nevertheless, as the use of meshes to treat uterovaginal prolapse can avoid anatomical distortion and the above mentioned problems related to this, the Applicant considers there are significant benefits in the use of meshes in the treatment of uterovaginal prolapse should it be possible to mitigate the problems associated with mesh treatment.

The applicant has recognised that there are a number of specific features of conventional meshes that exacerbate the problems of fistula, sinus, edge extrusion, infection etc., particularly when these meshes are implanted in the vaginal wall. The Applicant has therefore realised that it is possible to provide a surgical implant that has the benefits of mesh treatment, i.e. the avoidance of anatomical distortion and its related problems, and also minimises the above mentioned problems.

One specific problem with conventional meshes that the Applicant has recognised is that they have jagged or rough edges. The rough edges arise as conventional meshes are generally formed from sheets of multiple woven or intersecting fibres or strands. When the meshes are cut to size in manufacture or prior to fitting, the stray ends of the fibres or strands are left extending from the edge of the mesh, particularly where the edge is curved. In other words, the perimeter of the mesh comprises the spaced ends of the fibres or strands and is not smooth. It is thought that the jagged rough nature of the edges of the implant increases the likelihood of extrusion of the edge of the mesh *in situ*.

Conventional meshes are generally unnecessarily strong and substantial for use in the vaginal wall and of significant mass. This results in an unnecessary excess of foreign body material in the vaginal wall, increasing the risks associated with the placement of foreign bodies inside the human

body, such as the risk of infection. Likewise, the bulk of such meshes can undesirably result in discomfort for the patient as the mesh can often be felt when in position. This is of particular concern when a mesh is placed in sensitive vaginal tissues or near to bowel or bladder.

A further disadvantage of the meshes presently used to treat hernias relates to pore size. The pore size of meshes in use is unphysiological and does not encourage acceptance of the implant in the body.

It is a aim of the present invention to overcome problems associated with existing meshes used to treat hernias.

According to the present invention there is provided a surgical implant suitable for treatment of hernias, the implant comprising a mesh having a residual maximum mass density of $50g/m^2$.

Preferably the maximum mass density is less than $30g/m^2$. More preferably the maximum mass density is less than $25g/m^2$.

By minimising mass density of a mesh for use in treating hernias the advantages of using a mesh are still apparant whereas the disadvantages are lessened in that jagged and rough edges are minimised as is the risk of infection. The residual mass density is the mass density of the mesh after implantation.

Preferably the surgical implant mesh comprises strands and includes major spaces and pores.

The strands of the mesh may be formed by at least two filaments, the major spaces formed between the strands providing the surgical implant with the necessary strength, the filaments arranged such that pores are formed in the strands of the mesh.

Alternatively the strands may be formed by monofilaments which form loops which give rise to the pores.

Preferably strands are spaced by wider distance than the fibres or filaments of conventional meshes used in hernia repair.

Preferably the strands are spaced apart to form major spaces of between 1 to 10 mm.

More preferably the strands are spaced apart to form major spaces of between 2 to 8 mm.

The use of mesh having strands spaced between 1 to 10 mm apart has the advantage of reducing the foreign body mass that is implanted in the human body. Only sufficient tensile strength to securely support the defect and tissue being repaired is provided by the mesh.

It is desirable that the mesh of the present invention has a mass of between one tenth (1/10th)

and one hundredth (1/100th) that of a conventional, e.g. Prolene®, mesh of the same surface area. The mesh of the invention therefore avoids the unnecessary bulk of conventional meshes.

More specifically it is preferred that the mass density is less than $50g/m^2$, more preferably less than 30g/m and most preferably less than $20g/m^2$. It is also preferred that the strands of the mesh of the present invention are narrower than those of meshes of the prior art.

Preferably the strands have a diameter of less than 600μm.

In one embodiment the strands are arranged to form a diamond net mesh.

In an alternative embodiment the strands are arranged to form a hexagonal net mesh.

The strands and filaments are preferably warp knit.

In an alternative embodiment the strands are arranged to form a net mesh with suitable tensile strength and elasticity.

Preferably the strands are arranged to form a net mesh which has isotropic or near isotropic tensile strength and elasticity.

Preferably the filaments have a diameter of between 0.02 to 0.15 mm.

More preferably the filament of the mesh is of a diameter 0.08 to 0.1 mm.

This likewise has the advantage of reducing the overall bulk of the implant, and hence the amount of material retained in the human body.

Particular meshes which are embodiments of the present invention include warp knit diamond or hexagon net diamond net meshes. Four particular embodiments are set out below.

In two particular embodiments wherein the filaments are formed from polypropylene having a diameter of 0.07 - 0.08mm wherein the strands are spaced to form spaces of either 2mm or 5mm.

Alternatively, filaments are formed from polyester having a diameter of 0.09mm wherein the strands are spaced to form spaces of 5mm.

Alternatively, filaments are formed from polyester having a diameter of 0.05 - 0.07mm wherein the strands are spaced to form spaces of 2mm.

As the surgical implant is comprised of narrow members arranged to be spaced by relatively wide gaps, major spaces, tissue may be slow to grow into the mesh. It is desirable for the mesh to have

means for promoting tissue ingrowth. More specifically, it is desirable to provide pores in the strands of the mesh to aid tissue ingrowth and to which tissue may more easily adhere.

Preferably two filaments are interwoven/knitted to produce strands of the mesh comprising pores.

Alternatively at least three filaments are interwoven/knitted to produce strands of the mesh comprising pores.

For manufacturing reasons it is preferred that two filaments are used to form the pores in the strands of the mesh which aid tissue ingrowth, however if the one filament could be suitably knotted or twisted to form pores of suitable dimensions it is clear that this could be used to similar effect to form the strands of the mesh.

Preferably the pores in the strands are of between 50 to 200μm in diameter.

More preferably the pores are of between 50 to 75μm in diameter.

This is important in enabling efficient fibroblast throughgrowth and ordered collagen laydown in order to provide optimal integration into the body. This is discussed in detail in copending Patent Application No PCT/GB01/04554.

Rings or loops of material comprising pores of between 50 to 200µm may be adhered to or formed on the strands of the mesh to provide pores.

As mentioned above, reducing the mass of the mesh has distinct advantages in relation to the suitability of the mesh for implantation in the body, i.e. the reduction of foreign body mass and improving the comfort of the patient. However, the handling characteristics of such a mesh, e.g. the ease with which a surgeon can manipulate and place the surgical implant in its desired location in the body, can be poor in some circumstances. More specifically, a mesh having narrow members or strands that are widely spaced will inevitably be somewhat flimsy and lacking in rigidity compared to conventional meshes.

Ideally the implant should be formed from materials or uses technologies which provide the implant with Dual Phase Technology™, such that it has suitable surgical handling characteristics and is also of minimal mass and suited for implantation in the body. The implant may be formed from a range of materials to provide it with Dual Phase Technology™.
The term Dual Phase Technology™ refers to a means to provide temporary substance to the mesh. Depending on the type of Dual Phase Technology™ employed the benefits imported, in addition to allowing minimal residual mesh mass may include assisting the mesh to be handled and cut, minimising

the effect of rough edges, assisting placing the mesh in position and providing tackiness to assist in holding the mesh in position on implantation, thus minimising or negating the need for any additional fixation by suturing or adhesion.

In a preferred embodiment of the invention having improved handling characteristics, the implant therefore has an absorbable coating.
Preferably this coating encapsulates the mesh of the surgical implant.

Alternatively this coating is applied to at least one face of the mesh.

The coating, covering or layer of absorbable material stiffens and adds bulk to the mesh such that it is easier to handle.

As the coating, covering or layer is absorbable, it is absorbed by the body after implantation and does not contribute to the foreign body mass retained in the body. Thus, the advantages of a surgical implant having minimal mass are retained.

Preferably the coating, covering a layer absorbs within 48 hours following implantation.

The coating, covering or layer may comprise any suitable soluble and biocompatible material.

Suitable hydrogel materials can be obtained from First Water in the UK. A typical hydrogel being developed for use in this application is known as FIRST PHASE™ or PHASE 1™.

The absorbable material may be a soluble hydrogel such as gelatin,

Alternatively the absorbable material is a starch or cellulose based hydrogel.

In a further alternative the absorbable material is an alginate.

In a further alternative the absorbable material may contain hyaluronic acid.

The coating, covering or layer may have any thickness or bulk that provides the surgical implant with suitable handling characteristics.

Preferably, the coating is a sheet with a thickness greater than that of the mesh.

Suitable handling characteristics may also be provided to the mesh by a range of other methods. The surgical implant may comprise a mesh and a backing strip the backing strip releasably attachable to the mesh.

The backing strip may be formed from a range of materials including plastics.

The surgical implant may be releasably attachable to the backing strip by adhesive.

The releasable attachment of a backing strip to the mesh provides a more substantial and less flexible surgical implant that is more easily handled by a surgeon. Following suitable placement of the surgical implant the backing strip can be removed from the surgical implant, the surgical implant being retained in the body and the backing material being removed by the surgeon. The surgical implant can therefore benefit from reduced mass while still providing characteristics required for surgical handling.

In a further alternative the strands of the mesh of the surgical implant are comprised of bicomponent microfibres.

Preferably the bicomponent microfibres comprise a core material and surface material.

The composite or biocomponent fibres preferably comprise a nonabsorbable or long lasting absorbable core and a shorter lasting absorbable surface material.

Whereas any licenced materials amy be used, suitable materials presently available include polypropylene for the core and polylactic acid or polyglycolic acid for the surface materials.

Alternativley the bicomponent microfibres comprise an material which is rapidly absorbed by the body and a material which is not absorbed for a suitable longer period of time.

Preferably the surface material is capable of being absorbed by the body in a period of less than 48 hours.

Preferably the core material is capable of remaining in the body for a period of time sufficient to enable tissue ingrowth.

The surface material of the bicomponent microfibres or a portion of the composite polymers present during the insertion and placement of the surgical implant provides the surgical implant with characteristics required for surgical handling.

Following a period of insertion in the body, the surface material of the bicomponent microfibre is absorbed by the body leaving behind the reduced foreign mass of the core material of the strands of the mesh.

It is preferred that the surface material of the bicomponent microfibre is absorbed by the body within a number of hours such that only a core portion is left in the body for an extended length of time. Typically materials presently available which could be used to form the microfibres are absorbed by the body over a period of days or weeks.

The filaments of the mesh comprise a plastics or synthetic material.

Preferably the filaments of the mesh comprise of polypropylene or polyester.

Alternatively the filaments of the mesh comprise an absorbable material.

It can be appreciated that filaments which comprise in part of absorbable material would allow better surgical handling, but would enable the implant to also have minimal mass following implantation in the body.

Preferably the surgical implant comprises material that has memory.

Preferably the surgical implant has memory which urges the surgical implant to adopts a flat conformation.

Preferably the implant has a generally curved perimeter, i.e. to have few or no corners or apexes, as sharp corners increase the likelihood of edge erosion and infection. The specific shape will, however, vary according to the use to which the implant is to be put.

Due to the variety of sizes of such defects, and of the various fascia that may need repair by the implant, the implant may have any suitable size,

Preferably the surgical implant is of width between 1 cm to 10 cm and of length between 1 cm to 10 cm.

It may be desirable to provide a variety of implants having different sizes in order that a surgeon can select an implant of suitable size to treat a particular patient. This allows implants to be completely formed before delivery, ensuring, for example, that the smooth edge is properly formed under the control of the manufacturer. The surgeon would have a variety of differently sized (and/or shaped) implants to hand and select the appropriate implant to use after assessment of the patient.

Typically an anterior uterovaginal prolapse is ellipse shaped or a truncated ellipse whereas a posterior prolapse is circular or ovoid in shape.

Accordingly the implant shape may be any one of elliptical or tuncated ellipse, round, circular, oval, ovoid or some similar shape to be used depending on the hernia or polapse to be treated.

Different shapes are suitable for repairing different defects in fascial tissue and thus by providing a surgical implant which can be cut to a range of shapes a wide range of defects in fascial tissue can be treated.

Preferably the mesh can be cut to any desired size. The cutting may be carried out by a surgeon or nurse under sterile conditions such that the surgeon need

not have many differently sized implants to hand, but can simply cut a mesh to the desired size of the implant after assessment of the patient. In other words, the implant may be supplied in a large size and be capable of being cut to a smaller size, as desired.

In this regard, whilst the surgical implant of the invention is particularly useful for the repair of uterovaginal prolapse, it may be used in a variety of surgical procedures including the repair of hernias.

Preferably the surgical implant is suitable for use in the treatment of hernias including incisional and inguinal hernias and/or for the treatment of uterovaginal prolapse.

More broadly, the Applicant has therefore recognised that the implant can have any shape that conforms with an anatomical surface of the human or animal body that may be subject to a defect to be repaired by the implant.

As discussed a disadvantage of the meshes used in hernia repair is that they have jagged or rough edges. Due to the wide spacing between strands of the mesh described above and the small diameter of the filaments, the edge problems are mitigated to an extent by the present invention.

To further reduce edge problems it would be preferable if a mesh had a circumferential member which extends, in use, along at least part of the perimeter of the implant to provide a substantially smooth edge.

In other words, the mesh has at least one circumferential member (i.e. fibre, strand or such like) that extends around at least part of its circumference.

Preferably at least part of the perimeter of the implant is defined by the circumferential member,

Alternatively at least part of the perimeter of the implant is defined by more than one circumferential member, at the edge of the mesh.

The edge of the mesh, and hence the perimeter of the implant, can therefore be generally smooth and this has significant advantages over conventional surgical meshes. Specifically, the Applicant has recognised that an implant having a smooth edge is less likely to cause edge extrusion or erosion.

Any amount of the perimeter of the implant may be defined by the circumferential member(s).

However, in order to maximise the benefits of the implant of the invention, it is preferable that at least 50% of the perimeter of the implant is defined by the circumferential member(s)..

More preferably at least 80% of the perimeter of the implant is defined by the circumferential member(s).

Most preferably 100% of the perimeter of the implant is defined by the circumferential member(s).

The majority or the whole of the perimeter of the mesh being smooth minimises the risk of a rough edge causing edge erosion or infection.

The circumferential member(s) may be arranged in one of a variety of ways to provide the smooth edge or perimeter.

Preferably the circumferential members are arranged such that they each follow the edge of a desired shape of the surgical implant, the perimeter of the implant formed from as few members as possible.

This simplifies the construction of the mesh, which is desirable not only for manufacture, but also because simpler structures are less likely to have defects which might be problematic after implantation.

Preferably the perimeter of the mesh is defined, in use, by one circumferential member.

Preferably the mesh has a plurality of circumferential members arranged at different radial locations.

In order to provide an implant of given dimensions, the periphery of the mesh outward of the desired circumferential member is cut away such that one or more selected circumferential members form the perimeter of the implant as desired.

More preferably, the circumferential members are arranged concentrically.

A concentric arrangement of a plurailty of circumferential members conveniently allows maintenance of the shape of the implant for different sizes of implant and provides the mesh with an even structure.

The remainder of the structure of the mesh may take a variety of forms.

The circumferential members can be arranged to join with one another in order to form an integral mesh.

Alternatively the mesh may additionally comprise transverse members which extend across the circumferential members joining the circumferential members.

The transverse members may extend radially from a central point to the perimeter of the implant.

Alternatively, the transverse members may extend toward the perimeter of the implant.

Preferably the transverse members are arranged to provide substantially even structural strength and rigidity to the implant.

It may be desirable to secure the mesh in place once it has been suitably located in the patient.

Preferably the mesh can be sutured to strong lateral tissue.

Alternatively, the mesh may be glued in place using a biocompatible glue.

This is advantageous, as it is fairly quick to apply glue to the area around the surgical implant.

Preferably the mesh comprises at least one capsule containing biocompatible glue for securing the implant in place.

Preferably 4 capsules containing glue are provided around the perimeter of the surgical implant.

Preferably the capsules comprise hollow thin walled spheres of around 3 to 5 mm diameter including gelatin.

Preferably the glue is a cyanoacrylate glue.

Conventionally, open procedures have been preferred for the treatment of hernias with meshes, as relatively broad access is required to the site of

the defect to suitably implant and secure a mesh by sutures or such like.

However, it is desirable to treat hernias, as when carrying out any surgery, with as little trauma to the patient as possible. Thus, the use of minimally invasive techniques has been suggested for the treatment of hernias. However, such surgical techniques have not been considered to be useful in the treatment of uterovaginal prolapse with a mesh, as it has not been considered practical to position a mesh subcutaneously in the vaginal wall due to the difficulty in gaining direct access to this area.

According to another aspect of the present invention, there is provided a minimally invasive method of treating uterovaginal prolapse, the method comprising the steps;

making an incision in the vaginal wall close to the opening of the vaginal cavity and,

making a subcutaneous cut, through the incision, over and surrounding the area of the prolapse, which cut is substantially parallel to the vaginal wall; and

inserting a mesh according to the present invention, through the incision, into the space defined by the cut.

Thus, a mesh or the surgical implant such as that according to the invention can be inserted through a small incision (e.g. around 1cm to 2 cm in length) at or in the region of the periphery or opening of the vaginal cavity. An incision in this position is easier for a surgeon to access than an incision deeper in the vaginal cavity, yet the Applicant has realised that it is also convenient to treat vaginal prolapse by implanting a mesh in a surgical procedure carried out entirely through such an incision.

Preferably, the incision is at the anterior or posterior extremity of the prolapse sac of the vaginal cavity.

This is desirable as prolapse most often occurs in the anterior or posterior vaginal wall, so positioning the incision in such a location allows the most convenient access to these parts of the vaginal wall.

The provision of suitable handling characteristics for the mesh is particularly advantageous when the mesh is intended to be used in a conventional open surgical procedure, as the surgeon needs to handle the implant directly in order to place it in its desired location.

However, the suitable placement particularly in the treatment of uterovaginal prolapse, by minimally invasive techniques require the mesh to be as

flexible as possible and therefore to have no absorbable coating or encasement.

A flexible, less bulky mesh may be more easily handled by tools that may be used to carry out the procedure.

Tools that may be used to carry out this procedure have a number of specific needs that need to be met that are not presently met by conventional minimally invasive surgical tools.

These specific needs can best be understood by considering the steps of the surgical procedure of the invention in turn.

The incision is made in the vaginal wall at the opening of the vaginal cavity. This can be carried out using a conventional implement such as a scalpel. It is preferable that the incision is as small as possible as this reduces trauma to the patient.

A cut is then made in the vaginal wall over the defect causing the prolapse or hernia. For example, scissors or another specialised cutting tool can be inserted through the incision and manipulated to provide a cut over the defect. The cut is below the surface of the skin and may provide a space between an upper (or outer) layer and a lower (or inner) layer of the vaginal wall, or between the skin and

the vaginal wall, in the region of the defect, into which cavity the mesh can be inserted.

Next, the mesh is placed in the space defined by the cut. It is preferred that the mesh of the invention is supplied rolled up in order that it can be inserted through a small incision and unfurled *in situ*, i.e. in its intended position. Thus, it may be possible for the surgeon to insert the mesh through the incision by hand. However, this is likely to result in the incision needing to be large enough for the surgeon to insert a finger to manipulate the mesh in the space. This may cause unnecessary trauma to the patient and can be difficult for a surgeon to carry out.

According to another aspect of the present invention, there is provided a surgical tool for delivering a mesh subcutaneously through an incision, the tool being adapted to radially confine the mesh during delivery and being operable to release the mesh in its intended position.

Such a tool for placement of a mesh or the surgical implant of the present invention can insert and position the mesh or surgical implant in a convenient and controlled manner through a small incision. Furthermore, the incision through which the mesh is inserted need only be as large as the diameter of the tool, or the tool when carrying the mesh, which can be significantly smaller than where

a surgeon's finger must be able to fit through the incision.

Preferably the tool comprises a housing and unfurling means the housing and unfurling means insertable through an incision in the patient, the housing and unfurling means adapted to accommodate a rolled up mesh and separable to release the mesh the unfurling means capable of unfurling the rolled up mesh without any significant movement around the area of the incision

Preferably, the tool comprises two or more parts, the parts movable such that in a first position they house the mesh or surgical implant and, in a second position the mesh or surgical implant is released. More preferably the tool comprises two semi-circular channels, an inner channel having an external diameter suitable for fitting inside an outer channel.

The channels may be rotatable about a common axis such that in a first position the open faces of the channels face one another to form a closed housing and in a second position the inner channel sits inside the other channel to release the mesh.

Alternative the tool comprises a shaft and releasable securing means, the shaft adapted such that the mesh can be rolled around the shaft and releasable securing means to secure the rolled mesh in place.

In use, the tool is inserted through the incision with the mesh rolled around the outside of the shaft. Once the tool has been inserted, the mesh is released by turning the shaft to unroll the mesh at the same time as moving the shaft across the space in which the mesh is being placed.

A needle may be used to secure the free, outer end of the mesh whilst it is unfurled. The needle may be inserted through the vaginal wall to pin the mesh in place. Similarly, where the mesh is released from within a housing, needles may be used to ease the mesh out of the open housing.

In an alternate embodiment, the tool comprises two or more arms, each of which is releasably attached at one end to an edge of the surgical implant. The arms may be movable from a first position in which they radially confine the mesh to a second position to unfurl the mesh in its intended position.

In one example, the arms are pivotally interconnected such that they can be manipulated to move the ends of the arms from the first position to the second position.

In another example the arms may be arranged to extend radially outward from a housing to move from the first position to the second position. The extendable arms may comprise wires arranged to be extendable and retractable from and into the housing by operation at an end of the housing.

In another example, the arms may be resilient or sprung elements that can be released from the first position and move into the second position to which they are biased, i.e. to unfurl the mesh.

As can be appreciated, all of the above embodiments of the tool are able to unfurl the mesh without any significant movement around area of the incision. For example, the pivot can be arranged to coincide with the incision, the tool rolled around an arc centred at the incision or the arms operated or housing opened forward of the incision. Thus, the incision can be small as no lateral movement is required at the area of the incision.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is an illustration of a hernia;

Figure 2 is an illustration of the hernia of figure 1 when intra-abdominal pressure is raised;

Figure 3 is an illustration of the hernia of figure 1 after repair in accordance with the prior art;

Figure 4 is an illustration of the hernia of figure 1 after an alternate repair in accordance with the prior art;

Figure 5 is a schematic illustration of the female human vaginal area;

Figure 6 is a cross-sectional view of the female human vaginal area along the line A-A of Figure 5;

Figures 7a and 7b illustrate surgical implants according to the invention having a first shape;

Figures 8a, 8b, 8c and 8d illustrate surgical implants according to the invention having a second shape;

Figures 9a, 9b 9c and 9d illustrate surgical implants according to the invention having a third shape;

Figure 10 illustrates a first surgical tool according to the invention in cross-section;

Figure 11 illustrates a second surgical tool according to the invention;

Figure 12 illustrates a third surgical tool according to the invention; and

Figure 13 illustrates a fourth surgical tool according to the invention.

Referring to Figures 1 and 2, a hernia, vaginal prolapse or such like occurs when a fascial wall 1 ruptures, forming a defect 2, i.e. a weakening or, in this case, parting of the fascial wall 1. An organ 3, contained by the fascial wall 1 is then able to protrude through the defect 2. Such protrusion is illustrated in Figure 2 and occurs particularly when pressure within the cavity defined by the fascial wall 1 is raised. For example, in the case of an inguinal hernia, when a patient coughs, intra-abdominal pressure is raised and the intestines may be pushed through the defect 2 in the abdominal wall.

Whilst the organ 3 that may protrude through the defect 2 is usually still contained by some other membrane 4, the hernia, prolapse or such like is inevitably painful and liable to infection or other complications. An effective and desirable treatment is therefore to close the defect 2 and contain the organ 3 in its normal position.

Referring to Figure 3, hernias, vaginal prolapse and such like are conventionally repaired by providing sutures 5 across the defect 2 to join the tissues of the fascial wall 1. In addition, it may be firstly necessary to plicate (i.e. fold or reduce) the membrane 4 as this may have stretched due to distention of the organ 3. Plication of the membrane 4 corrects the stretching and helps to relieve pressure on the area of the defect 2 during healing as the membrane 4 can act to contain the

organ 3 to some extent. Plication is generally achieved by applying sutures 6 to the membrane 4.

Referring to Figure 4, it is also a known method of treating hernias to provide, additionally or alternatively to sutures, a mesh 7 across the defect 4. This allows for the defect 2 to be repaired without the parted tissues of the fascial wall 1 necessarily being brought together and for the defect to heal without the fascial wall 1 being pinched or tensioned to correct the defect 2.

Figure 5 schematically illustrates (a sagittal view of) the female human vaginal area. The vagina 8 is illustrated with its anterior portion (front) at the top of the diagram and the posterior portion (rear) at the bottom of the diagram. The opening of the urethra, or urethral meatus, 9 is at the forward or anterior end of the vagina 8. The central portion of the vagina 8 forms the vaginal cavity which terminates at the cervix 10. Spaced from the rearward or posterior end of the vagina 8 is the anus 11. Four areas A to D of the vaginal wall 12 are outlined in figure 5. These areas A to D are those areas of the vaginal wall 12 in which vaginal prolapse often occurs.

Referring to figure 6, which is a cross sectional view along the line A-A in figure 5, it can be more clearly seen that the wall 12 of the vagina 8 is bounded by the bladder 13 and urethra 14, the uterus 15, the small bowel 16 and rectum 17. The small

bowel 16 and rectum 17 are separated by the "Pouch of Douglas" PoD.

Area A is the lower one third of the anterior vaginal wall 12 (i.e. the one third nearest the entrance to the vaginal cavity) adjacent the bladder 13 and urethra 14. Prolapse in this area is referred to as anterior or, more specifically, urethracoele prolapse. Area B is the upper two thirds of the anterior vaginal wall 12. Prolapse in this area is referred to as anterior or, more specifically, cystocoele prolapse. The central area of the vaginal wall 12 in which the cervix 10 is located is adjacent the uterus 15 and prolapse in this area is referred to as central, uterine or vault prolapse. Area C is the upper one third of the posterior vaginal wall 12. This area of the vaginal wall 12 is adjacent the small bowel 16 and prolapse in this area is referred to as posterior or entreocoele prolapse. Finally, area D is the lower two thirds of the posterior vaginal wall and is adjacent the rectum 17. Prolapse in this area is generally referred to as posterior or rectocoele prolapse.

Conventionally, any of the above types of hernia have been treated by providing sutures in the area of the prolapse. For example, the extent of the defect causing the prolapse is first identified by the surgeon. Lateral sutures, i.e. sutures from one side to the other of the vaginal wall 12 as seen in figure 5 or right to left rather than anterior to

posterior, are provided across the area of the defect. This joins the parted tissues of the vaginal wall and repairs the defect. The organ protruding through the vaginal wall is therefore contained. Disadvantages of this technique include anatomical distortion of the vagina due to tensioning of the wall by the sutures to repair the defect.

A surgical implant for use in the repair of vaginal prolapse in accordance with an embodiment of the present invention comprises a mesh 20. The mesh is comprised of strands 22. The strands being less than 600 μm and approximately 150 to 600 μm in diameter. The strands are arranged such that they form a regular network and are spaced apart from each other such that for a diamond net a space of between 2mm to 5mm exists between the points where the strands of the mesh interact with each other (a). In a hexagonal net arrangement the space is between 2mm to 5mm between opposite diagonal points where the strands of the mesh interact (b).

It is preferable to space the strands as far as part as possible to allow blood to pass through the implant and reduce the mass of the implant, while providing the mesh with sufficient tensile strength and elasticity to be effective. It can therefore be appreciated that considerable variability in the maximum spacing between the strands can be achieved depending of the material from with the strands are

comprised and the net pattern in which the strands are arranged.

In the embodiment shown in figure 7a the strands are arranged in a diamond net pattern 24, however any pattern which provides suitable tensile strength an elasticity may be used.

For example a hexagonal net pattern may be used as shown in figure 7b.

Ideally in order to reduce the overall mass of the implant the strands 22 should have as narrow a diameter as possible while still providing the mesh 20 with suitable tensile strength and elasticity.

The strands 22 of the mesh 20 are comprised of at least two filaments 26 arranged to interact such that pores 28 are formed between the filaments 26.

The pores 28 formed between the filaments 26 are around 50 to 200 μm, such a spacing allowing fibroblast through growth to occur. This fibroblast through growth secures the implant 20 in place within the body. Additionally and importantly the suitably sized pores allow the implant 20 to act as a scaffold to encourage the lay down of new tissue. The lay down of new tissue promotes the healing of the hernia.

The filaments 26 may be formed from any biocompatible material. In this embodiment the

filaments 26 are formed from polyester, wherein each polyester filament 26 is around 0.09 mm in diameter.

In the embodiment shown the filaments 26 of the strands 24 are knitted together using warp knit to reduce the possibility of fraying of the filaments 26 and strands 24.

Alternative suitable materials of which the filaments may be formed include polypropylene.

Suitable materials from which the mesh can be made: provide sufficient tensile strength to support a fascial wall during repair of a defect in the fascial wall causing a hernia; are sufficiently inert to avoid foreign body reactions when retained in the human body for long periods of time; can be easily sterilised to prevent the introduction of infection when the mesh is implanted in the human body; and have suitably easy handling characteristics for placement in the desired location in the body.

The fine warp knit of the filaments 26 provides a surgical implant which is flexible in handing, which can be easily cut into different shapes and dimensions. As the strands 24 are formed using warp knit the possibility of fraying of the edge of the surgical implant 20 following production or cutting of the surgical implant 20 is reduced.

Other methods of reducing fraying of the filaments 24, not arranged to form the strands using warp knit, following cutting or production of the implant are heat treatment, laser treatment or the like to seal the edges of the surgical implant.

The mesh 20 may be supplied in any shape or size and cut to the appropriate dimensions as required by the surgeon.

It can be appreciated that cutting of the mesh will produce an unfinished edge 30. Due to the sparse nature of the strands that form the mesh and their narrow diameter this unfinished edge does not suffer from the same problems as edges of meshes of the prior art.

In other words the edge produced is not rough and jagged such that it increases the likelihood of extrusion of the edge of the mesh *in situ* or the chance of infection.

As discussed an advantage of the mesh of the present invention is that it allows the production of a mesh suitable for use in hernia repair which allows substantially less foreign material to be left into the body.

However, the mesh being flexible and insubstantial is less suitable for allowing easy handling of the mesh directly by a surgeon. Referring to figure 8a

and 8b the mesh described above may be treatable using an absorbable coating 32.

The absorbable coating 32 comprises a layer of absorbable material having a thickness greater than that of the strands 22 of the mesh 20. For example, the thickness of the layer of absorbable material may be around 1 to 2 mm. The strands 22 of the mesh 20 may be entirely embedded in the absorbable coating 32 such that the outer surface of the mesh 20 is covered entirely of the absorbable coating 32.

In effect the entire surgical implant is encased in the absorbable coating as shown in figure 8b.

Thus, the surgical implant has no gaps or holes on its surface. This has the advantage of reducing the likelihood of bacteria becoming lodged on the strands 22 of the mesh 20 before implantation of the mesh 20. Furthermore, the absorbable coating 32 makes the mesh 20 more substantial and less flexible such that it is more easily handled by a surgeon. This is particularly useful when it is desired to place the mesh in a desired location in a conventional, open surgical procedure.

In an alternative embodiment shown in figure 8a the absorbable coating 32 comprises a layer of absorbable material applied to one face 34 of the mesh 20, such that the mesh has a first face 34 on which the absorbable material has been applied and a second face 36 on which the absorbable material has

not been applied such that the first and second faces 34 and 36 each have different characteristics.

It can also be envisaged that the surgical implant is provided with improved surgical handling qualities by a range of other methods. Such methods including, the releasable attachment of the mesh 20 to a backing strip 40. This embodiment is shown in figure 8c.

The backing strip may be formed from plastics material and is adhered to the surgical implant using releasable adhesive.

In a similar fashion to the absorbable coating the backing strip 40 causes the mesh 20 to be more substantial and less flexible such that it is more easily handled by a surgeon. Following the suitable placement of the mesh 20 the backing strip 40 can be removed from the mesh 20, the mesh 20 being retained in the body and the backing material 40 being removed by the surgeon. Application of the backing strip 40 to the mesh 20 means the mesh 20 benefits from reduced mass but that the mesh 20 and backing strip 40 together give characteristics required for surgical handling.

In a further embodiment the filaments of the mesh may be comprised from bicomponent microfibres 50 or composite polymers 60. These technologies provide the implant with dual phase technology.

As shown in figure 8d the bicomponent microfibres 50 comprise a core 52 (cutaway section shows core region)and surface material 54. The surface material 54 is designed such that it is absorbed by the body in a matter of hours, while the core material 52 remains in the body for a longer period to enable tissue ingrowth.

Suitable bicomponent microfibres 50 include a polypropelene non absorable portion and a polylactic acid absorbable portion.

The surface material 54 is present during the surgical procedure when the mesh 20 is being inserted and located in the patient, and provides the mesh with characteristics desirable for surgical handling. Following a period of insertion in the body, typically a few hours, the surface material 54 is absorbed into the body leaving only the core material 52 of the filaments 26 in the body. The core material of the filament having reduced foreign mass in comparison to meshes of the prior art or the mesh 20 when it also includes the surface material 54.

As shown in figure 8e the mesh of the surgical implant may be formed composite polymers 60. As described for the bicomponent microfibres 50, composite polymers 60 provide the surgical implant with dual phase technology. A first face 62 of the mesh 20 thus having particular characteristics such as flexibility and elasticity, while a second face

64 of the mesh 20 provides the mesh 20 with characteristics which improved the surgical handling of the mesh 20 such as strength and robustness. The cutting of the mesh described causes an unfinished edge of the mesh to be produced. This unfinished mesh not being as likely to cause the same problems as the rough and jagged edges of the implants of the prior art, due to the fewer strands, smaller diameter filaments and treatment of the mesh with absorbable coating which protects the tissue from the mesh during the surgical procedure when damage is most likely to occur.

Referring to 9a, a further embodiment of the mesh may comprise strands as discussed and more specifically, perimeter strands. Typically the mesh is circular or the like in shape and thus this perimeter strand can be generally referred to as a circumferential strand 70.

In the example shown in figure 9a one strand runs around the circumference of the oval shape of the mesh 20. In another embodiment, several circumferential strands 70 may be present, each circumferential strand 70 may extend over one side of the oval mesh 20, i.e. around half the circumference of the mesh.

As shown in figure 9b the circumferential strands 70 are arranged concentrically and each extends around the mesh 20 at a different radial location.

An outer circumferential strand 70 extending around the perimeter of the mesh 20, and further circumferential strands 72 and 74 are arranged inwardly of the outer circumferential strand forming a perimeter spaced by a distance (a). The distance a between adjacent circumferential members 70, 72 and 74, can vary and in this example is 20 mm.

Transverse strands 76 extend from the centre of the oval mesh 20 to points on the perimeter of the mesh 78. In this example, four transverse strands 76 are provided across the diameter of the mesh 20, dividing the mesh 18 into eight angularly equal portions.

The mesh 20 of this embodiment may be formed from materials as previously described. Depending on the material chosen the mesh may be woven, knitted or extruded as one piece, or individual or groups of strands can be extruded separately and joined to one another.

Such a construction as described above provides a mesh 20 with sufficient tensile strength to repair defects causing vaginal prolapse whilst having minimal bulk. Similarly, such a construction provides a suitably flexible yet resilient mesh for handling using the surgical tools described below. Referring to figures 9c and 9d, meshes 80, 82 of in the shape of the outline having angled sides respectively, rather than oval, are illustrated.

These meshes have a similar structure to that described with reference to figure 9a and b. However, the mesh has a perimeter member 80 having angled sides. Further it may have transverse members arranged only to extend towards the perimeter of the mesh, rather than all being across the diameter of the mesh. This provides a more uniform structure. More specifically, referring to figure 9d the mesh has a transverse member 84 extending along its axis of symmetry, a transverse member 86 bisecting the axis of symmetry, and four further transverse members 88 extending from the axis of symmetry to the perimeter of the mesh 90.

In addition to the pores provided by the combination of filaments 26 which form the strands 22, pores can be provided by rings of polypropylene positioned at the intersection of the circumferential and transverse members.

Alternatively the pores may be formed by the spacing of the transverse members, such that pores of a size 50-200μm suitable for enabling tissue ingrowth exist between the transverse members.

To secure the mesh to a suitable location in the body a number of methods can be used. The tackiness of the absorbable coating may hold the mesh suitably until it is secured by tissue ingrowth.

Alternatively the surgical implant can have capsules 100(not shown) of biocompatible glue for securing

the mesh 20 in place. In this example, six capsules 100 comprising spheres having a diameter of 4 mm and made from a rapidly absorbable material are provided around the perimeter of the mesh 20. On placement in the body, the capsules 100 dissolve and release a biocompatible glue contained within to secure the mesh 20 in place.

Referring to figure 10, a tool 200 for inserting one of the meshes described (usually without an absorbable coating 32) comprises two channels 202, 204. The channels 202, 204 are semi-circular in cross-section and the channel 202 has a diameter slightly smaller than the diameter of channel 204. The channels are interconnected such that the channel 202 can be rotated inside the channel 204. In use, the mesh 20 is rolled up and placed in the space formed by the channels 202,204 in a first position in which the open sides of the channels face one another to form a housing or tube. After insertion into the desired location, channel 204 is rotated inside the channel 202 to release the mesh 20.

Referring to figure 11, an alternative tool 210 for inserting one of the meshes described comprises an elongate housing 212 around which the mesh is rolled and secured. The tool 210 has means for trapping an edge of the mesh 20 to secure it on the housing of the tool 212, such as a groove 214. In use, once the mesh 20 has been rolled around the housing of the tool 210 it may be secured by a removable clip

or other such retaining means (not shown). After insertion of the tool 210 into the desired location, the mesh 20 is released and the tool 210 is rotated to unfurl the mesh 20.

Referring to figure 12, another alternative tool 220 for inserting one of the meshes described above in the body comprises two arms 222 pivotally interconnected by a pivot 224. One end of each arm 226 has means for being releasably attached to the mesh 20. The other end of each arm 228 is operable to move the ends that may be attached to the mesh 20 toward or away from one another by rotation around the pivot 224. When the ends of the arms 226,228 to which the mesh 20 can be attached are moved to a position in which they are close to one another, the tool 220 is substantially elongate. Furthermore, the mesh 20 is radially confined by the arms. Once the mesh 20 has been inserted into position, the arms 226,228 can be manipulated to move the ends to which the mesh 20 can be attached apart to unfurl the mesh 20 in its intended position.

Referring to figure 13, another tool 230 for inserting one of the meshes described above in its desired location comprises an elongate housing 232 having a number of pairs of holes 234 spaced along its length (in this example three pairs) at the distal end of the tool 230. The housing 232 is hollow and contains a number (in this case three) of pairs of wires 236, made from polypropylene for example, which extend along the length of the

housing 232 and out through the pairs of holes 234. The wires 236 also protrude from the proximal end of the housing such that they can be pushed and pulled in and out of the housing 232. The ends of the wires 236 that protrude from the holes 234 have means for releasably attaching to points near the perimeter of the mesh 20.

In use, the wires 236 are attached to the mesh 20 and retracted by pulling them back through the housing 30 such that the mesh 20 is radially confined close to the housing 232. Once the tool 230 has been inserted into the intended position, the wires 236 are pushed into the housing 232 and consequently out through the holes 234 to urge the mesh 20 away from the housing 232. Thus, the mesh 20 can be unfurled in its desired location in the body.

Referring once again to figure 5 in order to repair a urethracoele prolapse i.e. a defect in the area A of figure 5, the surgeon first locates the defect by examining the patient in the conventional manner. The extent of the defect can then be ascertained and, if necessary, a suitable template used to estimate the shape and dimensions of a preferred surgical implant to repair the defect. A suitably shaped surgical implant can then be selected.

The meshes described above are, in this example, supplied in a single size. After examination of the patient and estimation of the desired dimensions of

the preferred mesh, the surgeon cuts the mesh to the preferred size.

Where the mesh comprises a circumferential member 70 the cut made in the mesh is through the transverse members 76 just outward of the circumferential member 70 corresponding most closely with the preferred size of mesh. Thus, regardless of the size to which the mesh is to be cut, a circumferential member 70 defines the perimeter of the mesh, and the perimeter of the mesh is substantially smooth. This desirably reduces the likelihood of infection or edge erosion once the mesh is inserted in the body.

The surgeon then attaches the mesh to or inserts the mesh with one of the insertion tools described herein. For example, the mesh is rolled up and placed within the insertion tool 200 illustrated in figure 10, wrapped around the insertion tool 210 illustrated in figure 11, attached to the ends of the arms 222 of the insertion tool 220 illustrated in figure 12 or attached to the ends of the wires 236 of the insertion tool 230 illustrated in figure 13.

An incision 9 is then made in the vaginal wall 12 at the forward most portion of the vaginal wall 12 adjacent the opening of the vaginal cavity. A cutting implement (not illustrated), such as scissors or a specialised cutting tool, is/are then inserted through the incision 9 into the area A,

i.e. the lower portion of the anterior vaginal wall 12. Using the cutting implement, a cut is made in the area A parallel with the surface of the vaginal wall 12. In other words, a space is opened up in the vaginal wall 12 over the area of the defect in the vaginal wall 12. The cutting implement is then withdrawn and the mesh 20 is inserted in the space defined by the cut.

Where the insertion tool 200 illustrated in figure 10 is used, the tool 200 is inserted into the area A and the channel 202 rotated to a position within the channel 204 to release the mesh 20. The insertion tool 200 can then be retracted and the mesh unfurls due to its inherent resilience or flat memory. Should it be required to help the mesh 20 to unfurl, or slightly re-position the mesh 20 defect 2, an elongate tool (not shown) may be inserted through the incision 9 or needles may be introduced directly through the vaginal wall 12 to manipulate the mesh 20. This procedure can be viewed laproscopically through the incision 9 if desired.

Where the insertion tool 210 illustrated in figure 11 is used, it is desirable for the insertion tool 210 to be inserted to one side of the space defined by the cut. The mesh 20 is then released and a needle inserted through the vaginal wall to hold the released edge of the mesh 20 in position. The tool 210 is then rolled across the space defined by the cut in an arc having a centre of rotation around the incision 9. Thus, the mesh 20 is unfurled, but no

significant movement is required around the incision 9.

Where the insertion tool 220 illustrated in figure 12 is used, the insertion tool 220 is simply inserted through the incision 9 and opened to expand the mesh 20 into its desired location. The mesh 20 is released from the insertion tool 220 which can then be closed and withdrawn through the incision 9.

Finally, where the insertion tool 250 illustrated in Figure 13 is used, the mesh 20 is retracted by withdrawing the wires 236 through their holes 234 and the mesh is inserted through the incision 9. Once the insertion tool 230 has been inserted into its desired location, the wires 236 are urged forward and out through the holes 234 to expand the mesh in its intended position. The wires 236 can then be released from the mesh 20, withdrawn into the housing 232 and the tool 230 withdrawn through the incision 9.

Once the mesh 20 is in place, the incision may be closed.

However, it can be desirable to secure the 20 in place, rather than rely on the mesh 20 remaining in its desired location of its own accord. In one example, sutures are therefore be placed either laproscopically through the incision 9 or directly through the vaginal wall 12 to hold the mesh 20 in place. In another example, glue capsules provided

on the mesh 20 dissolve to secure the mesh 20 to the tissue surrounding the space defined by the cut, or such capsules may be punctured by needles inserted directly through the vaginal wall 12.

The surgical implant described herein is advantageous over the meshes of the prior art in several ways.

In particular the mesh of the present invention includes smoother edges, the polyester material of the present invention being softer than polypropylene. Further, the filaments of the present invention are narrower in diameter enabling them to be more pliable than the strands of the meshes of the prior art. This causes the edge or edges of the mesh of the present invention to have fewer jagged edges and thus be smoother that the edges of meshes or the prior art.

In addition encasement of the mesh in an absorbable coating further protects the tissue both during placement and for a period of time after placement of the surgical implant.

Dual Phase Technology™ such as encasement in an absorbable coating or as otherwise discussed herein provides the implant with good handling characteristics, further it enables the implant to be more easily cut. As described above an absorbable coating may protect the tissues around where the implant is to be located both during

placement and for a period of time following placement of the implant in the tissue.

Dual Phase Technology™ may also provide the implant with memory. This memory may allow the implant to be more easily placed flat on the tissue. Further the dual phase technology such as an absorbable coating may provide the implant with mild adhesive properties or tackiness which would aid both the locating and securing of the implant in the tissue.

The surgical implant described herein thus allows tension free repair of hernias, particular vaginal prolopse, with minimum pain. This allows the procedure to be performed under local anaesthetic in an out patient or office setting.

Whilst the above embodiments of the invention have been described with reference to vaginal prolapse, the mesh and surgical tools may equally be used to repair any bodily hernia. Furthermore, whilst the above procedure has been described in relation to a urethrocoele prolapse, prolapse in other parts of the vaginal wall 12 can be treated through incisions elsewhere in the vaginal wall, or other bodily hernias through suitable incisions in the appropriate tissue.

Claims

1. A surgial implant suitable for treatment of hernias, the implant comprising a mesh comprising strands having a maximum residual mass density of $50g/m^2$.

2. An implant as claimed in claim 1 wherein the mesh has a maximum residual mass density of less than $30g/m^2$.

3. A surgical implant as claimed in claims 1 or 2 wherein the mesh comprises strands and includes major spaces and pores, the spaces existing between the strands and pores formed within the strands.

4. An implant as claimed in any preceding claim wherein strands are formed from at least two filaments.

5. A surgical implant as claimed in any preceding claim wherein the strands are spaced apart to form major spaces of 1 to 10 mm.

6. A surgical implant as claimed in any preceding claim wherein the strands have a diameter of less than 600μm.

7. A surgical implant as claimed in any preceding claim wherein the strands are arranged to form a warp knit diamond or hexagonal net mesh.

8. A surgical implant as claimed in any preceding claim wherein the strands are arranged to form a net mesh which has isotropic or near isotropic tensile strength and elasticity.

9. A surgical implant as claimed in any preceding claim wherein the filaments have a diameter of between 0.02 to 0.15 mm.

10. A surgical implant as claimed in any preceding claim wherein the filament of the mesh is of a diameter 0.05 to 0.1 mm.

11 A surgical implant as claimed in any preceding claim wherein a monofilament or at least two filaments are interwoven/knitted such that the strands of the mesh comprise pores.

12. A surgical implant as claimed in any preceding claim wherein the pores in the strands are of between 50 to 200μm in diameter.

13. A surgical implant as claimed in any preceding claim further comprising rings of material comprising pores of between 50 to 200μm adhered to on the strands of the mesh to provide pores.

14. A surgical implant as claimed in any preceding claim wherein the pores in the strands are of between 50 to 75μm in diameter.

15. A surgical implant as claimed in any preceding claim wherein the filaments of the mesh comprise a plastics material.

16. A surgical implant as claimed in any preceding claim wherein the filaments of the mesh comprise a synthetic material.

17. A surgical implant as claimed in any preceding claim wherein the filaments of the mesh comprise an absorbable material.

18. A surgical implant as claimed in any of claims 1 to 16 wherein the filaments of the mesh comprise polypropylene.

19. A surgical implant as claimed in any of claims 1 to 16 wherein the filaments of the mesh comprise polyester.

20. A surgical implant as claimed in any preceding claim wherein the implant has an absorbable coating which degrades within 48 hours.

21. A surgical implant as claimed in claim 20 wherein the absorbable coating encapsulates the mesh of the surgical implant.

22. A surgical implant as claimed in claim 20 wherein the absorbable coating is applied to at least one face of the mesh.

23. A surgical implant as claimed in claims 20 to 22 wherein the absorbable coating comprises any suitable soluble and biocompatible material.

24. A surgical implant as claimed in claims 20 to 23 wherein the absorbable coating is a soluble hydrogel such as gelatin.

25. A surgical implant as claimed in claims 20 to 23 wherein the absorbable coating is a starch or cellulose based gel.

26. A surgical implant as claimed in claims 20 to 23 wherein the absorbable coating is an alginate.

27. A surgical implant as claimed in claims 20 to 26 wherein the coating is of a thickness greater than that of the mesh.

28. A surgical implant as claimed in any preceding claim comprising a backing strip wherein the backing strip is releasably attachable to the mesh.

29. A surgical implant as claimed in claim 28 wherein the backing strip is formed from plastics.

30. A surgical implant as claimed in claims 28 or 29 wherein the surgical implant is releasably attachable to the backing strip by adhesive.

31. A surgical implant as claimed in any preceding claim wherein the strands of the mesh are comprised of bicomponent microfibres.

32. A surgical implant as claimed in claim 31 wherein the bicomponent microfibres comprise a core and surface material.

33. A surgical implant as claimed in claim 32 wherein the surface material is capable of being absorbed by the body in a period of less than 48 hours.

34. A surgical implant as claimed in claims 32 or 33 wherein the core material is capable of remaining in the body for a period of time sufficient to enable tissue ingrowth.

35. A surgical implant as claimed in claim 32 wherein the surface material is polylactic acid and the core material is polypropylene.

36. A surgical implant as claimed in any preceding claim wherein the surgical implant comprises material that has memory.

37. A surgical implant as claimed in claim 36 wherein the surgical implant has memory which urges the surgical implant to adopt a flat conformation.

38. A surgical implant as claimed in any preceding claim wherein the implant has a generally curved perimeter.

39. A surgical implant as claimed in any preceding claim wherein the surgical implant is of width between 1 cm to 10 cm and of length between 1 cm to 10 cm.

40. A surgical implant as claimed in any preceding claim wherein the implant is any one of round, circular, oval, ovoid eliptical or truncated eliptical or some similar shape.

41. A surgical implant as claimed in any preceding claim wherein the mesh can be cut to any desired shape.

42. A surgical implant as claimed in any preceding claim wherein the mesh has at least one circumferential member which extends, in use, along at least part of the perimeter of the implant to provide a substantially smooth edge.

43. A surgical implant as claimed in claim 42 wherein at least part of the perimeter of the implant is defined by the circumferential member.

44. A surgical implant as claimed in claims 42 or 43 wherein at least 50% of the perimeter of the implant is defined by the circumferential member(s).

45. A surgical implant as claimed in claims 42 to 44 wherein at least 80% of the perimeter of the implant is defined by the circumferential member(s).

46. A surgical implant as claimed in claims 42 to 45 wherein 100% of the perimeter of the implant is defined by the circumferential member(s).

47. A surgical implant as claimed in claims 42 to 46 wherein the perimeter of the mesh is defined, in use, by one circumferential member.

48. A surgical implant as claimed in claims 42 to 47 wherein the mesh has a plurality of circumferential members arranged at different radial locations.

49. A surgical implant as claimed in claim 48 wherein the circumferential members are arranged to join with one another in order to form an integral mesh.

50. A surgical implant as claimed in claim 42 to 49 wherein the mesh comprises transverse members which extend across the circumferential members joining the circumferential members.

51. A surgical implant as claimed in claim 50 wherein the transverse members extend radially from a central point to the perimeter of the implant.

52. A surgical implant as claimed in claim 50 or 51 wherein the transverse members extend toward the perimeter of the implant.

53. A surgical implant as claimed in any preceding claim wherein the mesh can be glued in place using a biocompatible glue.

54. A surgical implant as claimed in any preceding claim comprising at least one capsule containing biocompatable glue for securing the implant in place.

55. A surgical implant as claimed in claim 54 comprising four capsules containing glue provided around the perimeter of the surgical implant.

56. A surgical implant as claimed in claims 54 or 55 wherein the capsules comprise hollow thin walled spheres of around 3 to 5 mm diameter including gelatin.

57. A surgical implant as claimed in claims 54 to 56 wherein the glue is a cyanoacrylate glue.

58. A minimally invasive method of treating uterovaginal prolapse, the method comprising the steps;

making a 1-2cm length incision in the vaginal wall close to the opening of the vaginal cavity and,

making a subcutaneous cut, through the incision, over and surrounding the area of the prolapse, which cut is substantially parallel to the vaginal wall; and

inserting a mesh according to the present invention, through the incision, into the space defined by the cut.

59. A method of treating uterovaginal prolapse as claimed in claim 58 wherein the incision is at the posterior extremity of the prolapse sac of the vaginal cavity.

60. A method of treating uterovaginal prolapse as claimed in claim 58 wherein the incision is at the anterior extremity of the prolapse sac of the vaginal cavity.

61. A surgical tool for delivering a surgical implant as described in claims 1 to 57 subcutaneously through an incision, the tool being adapted to radially confine the surgical implant during delivery and being operable to release the mesh in its intended position.

62. A surgical tool as claimed in claim 61 comprising a housing and unfurling means the housing and unfurling means insertable through an incision in the patient, the housing and unfurling means adapted to accommodate a rolled up mesh and separable to release the mesh, the unfurling means

capable of unfurling the rolled up mesh without any significant movement around the area of the incision

63. A surgical tool as claimed in claim 61 or 62 comprising two or more parts, the parts movable such that in a first position they house the mesh or surgical implant and, in a second position the mesh or surgical implant is released. More preferably the tool comprises two semi-circular channels, an inner channel having an external diameter suitable for fitting inside an outer channel.

64. Use of an implant as claimed in any of claims 1 to 57 in the treatment of inguinal hernia, incisional hernia or uterovaginal prolapse.

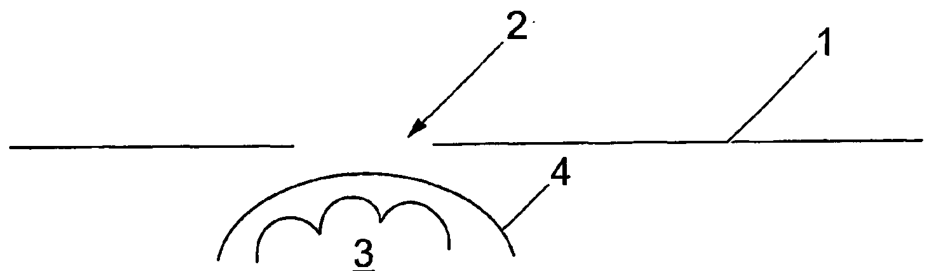


Fig. 1

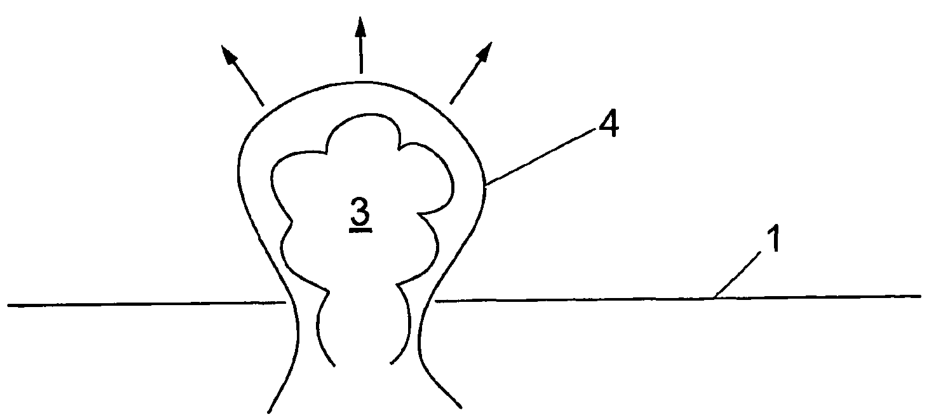


Fig. 2

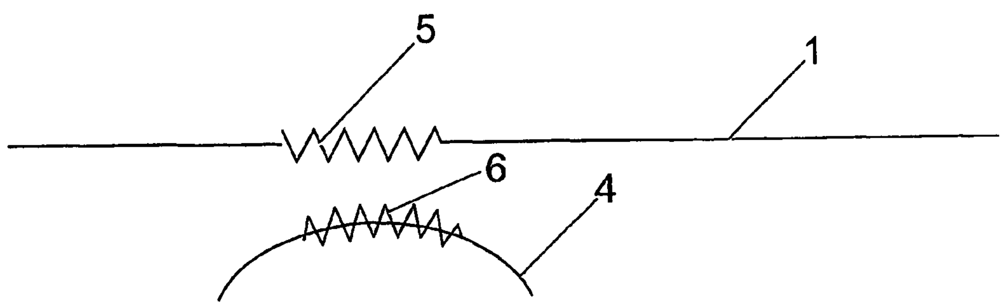


Fig. 3

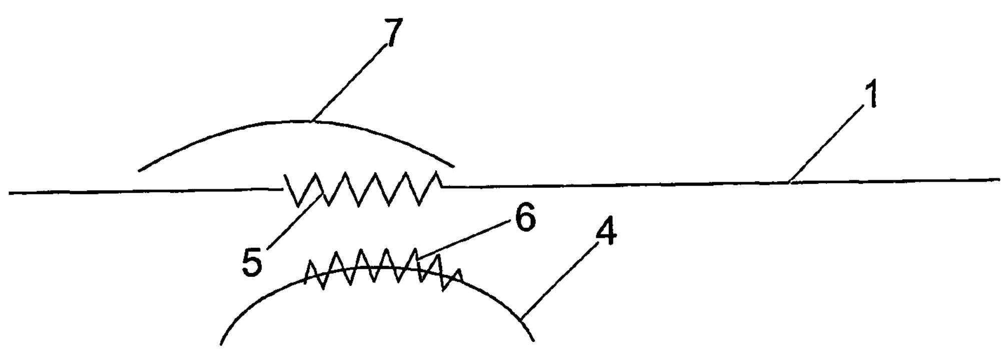
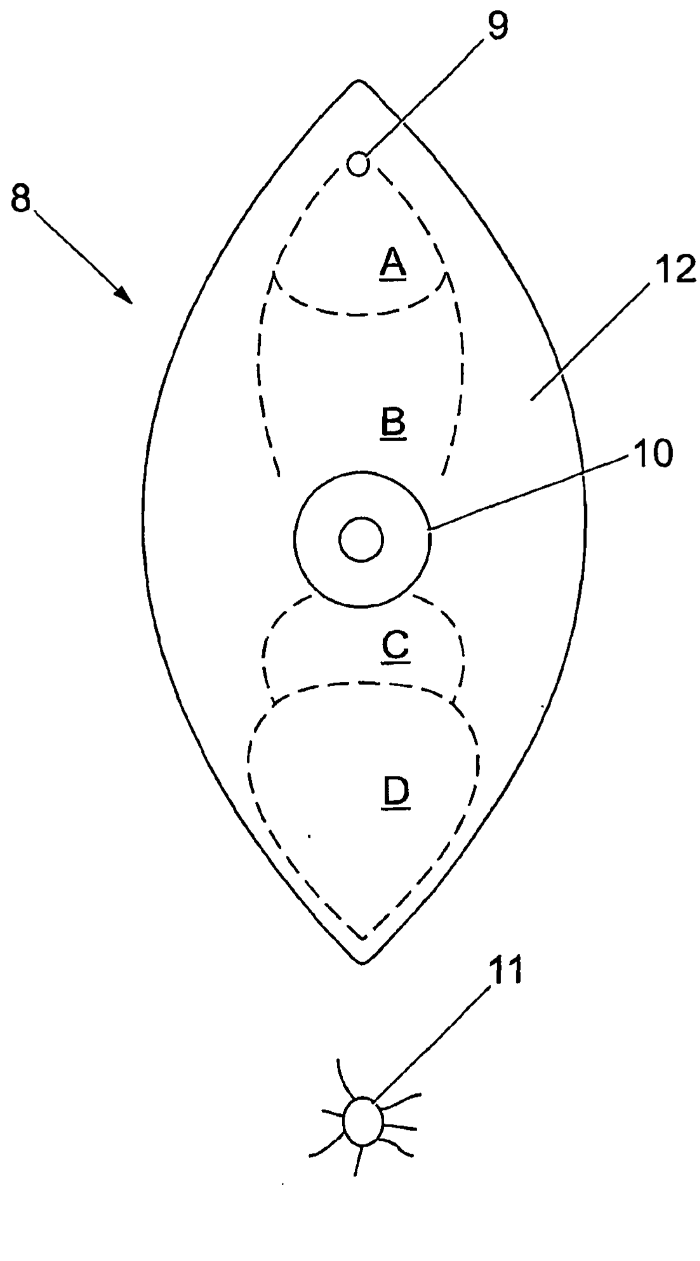


Fig. 4



SECTION A-A

Fig. 5

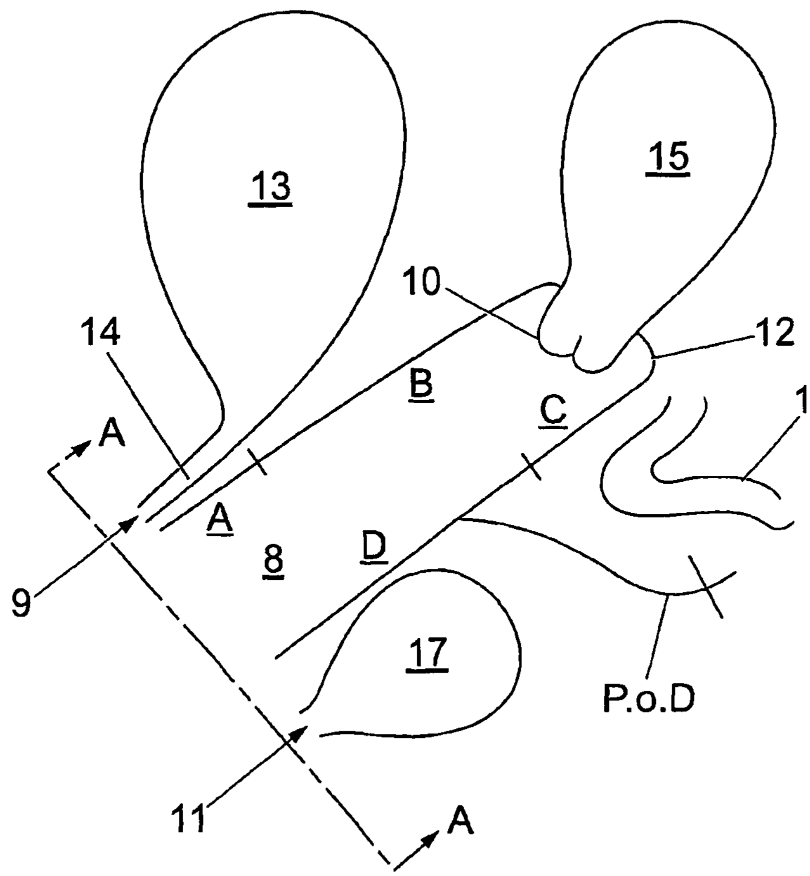


Fig. 6

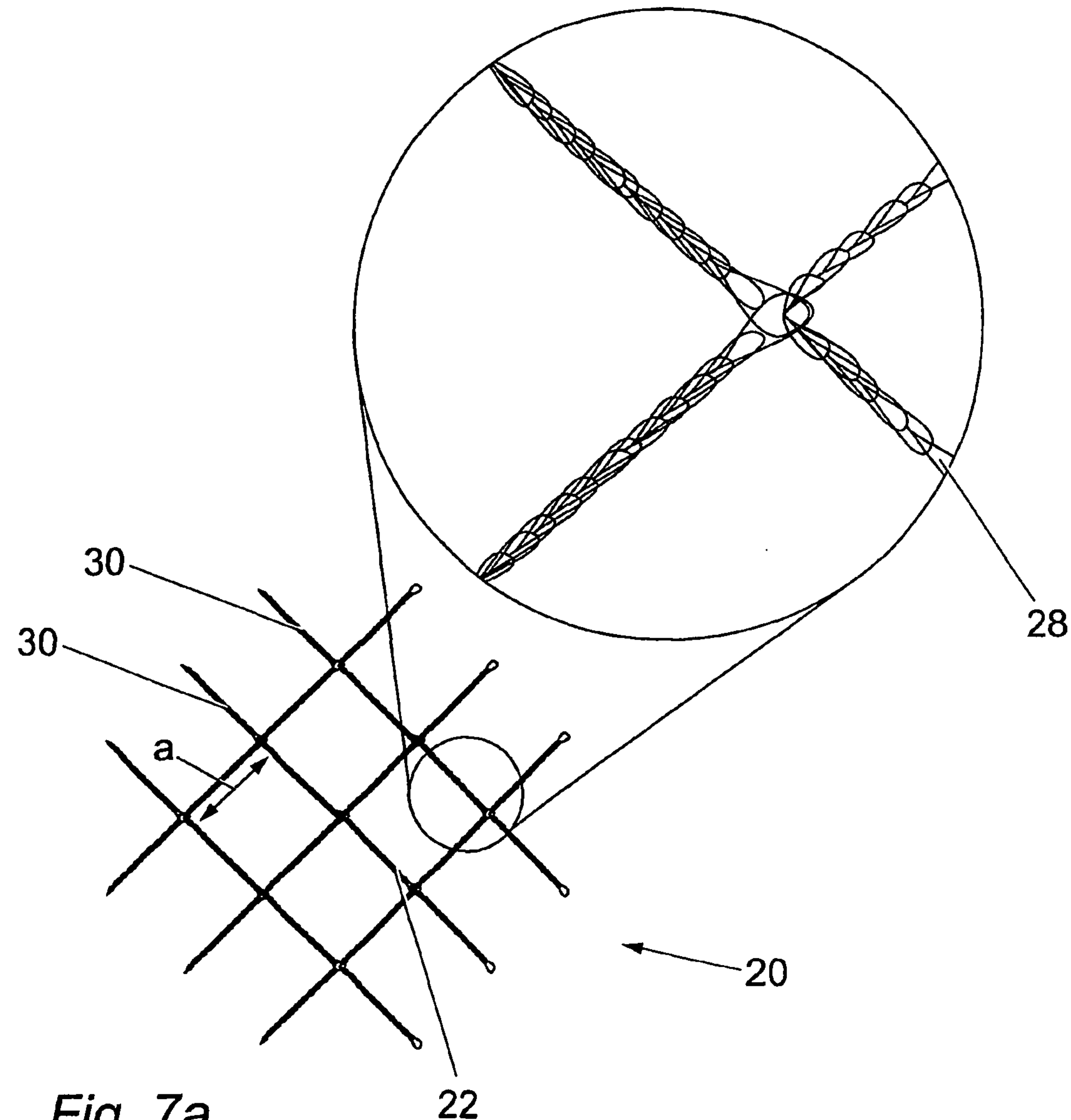


Fig. 7a

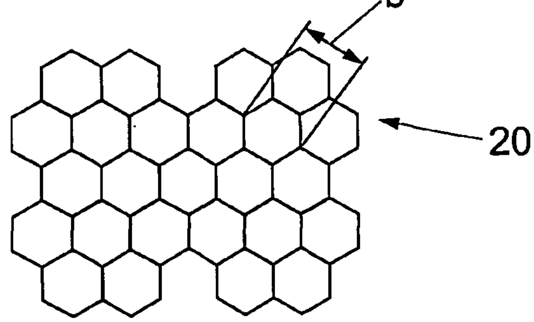


Fig. 7b

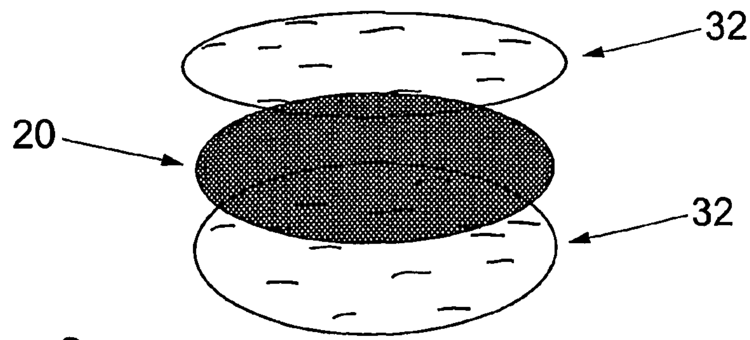


Fig. 8a

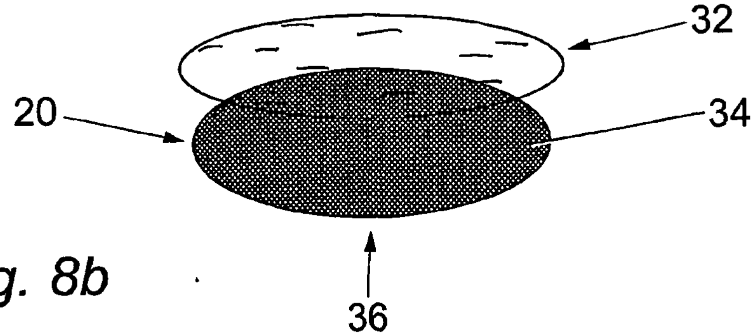


Fig. 8b

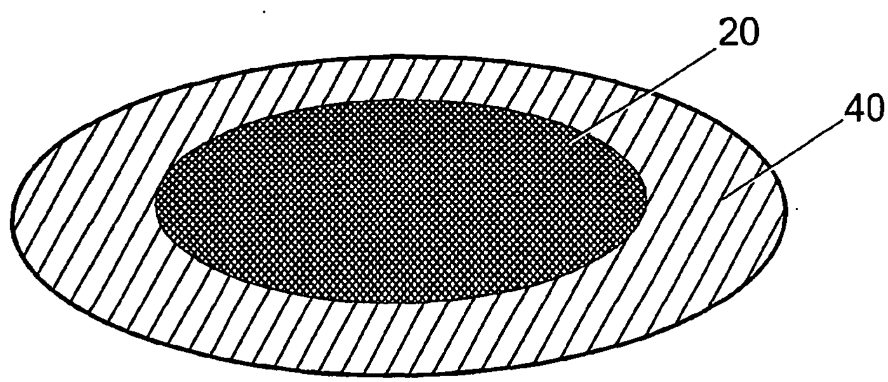


Fig. 8c

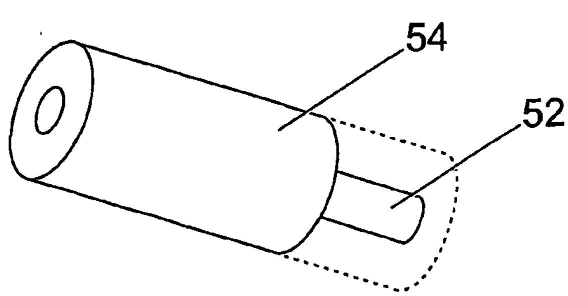


Fig. 8d

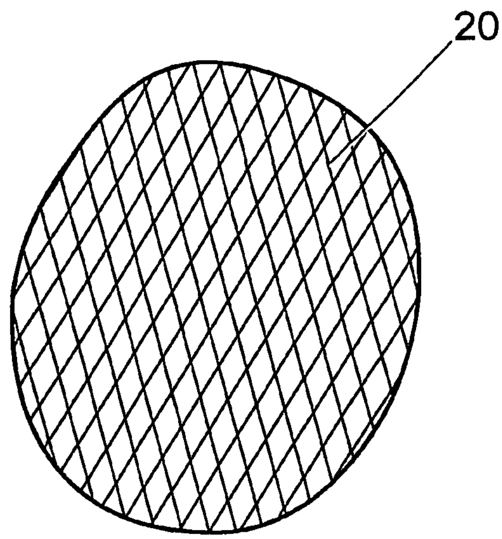


Fig. 9a

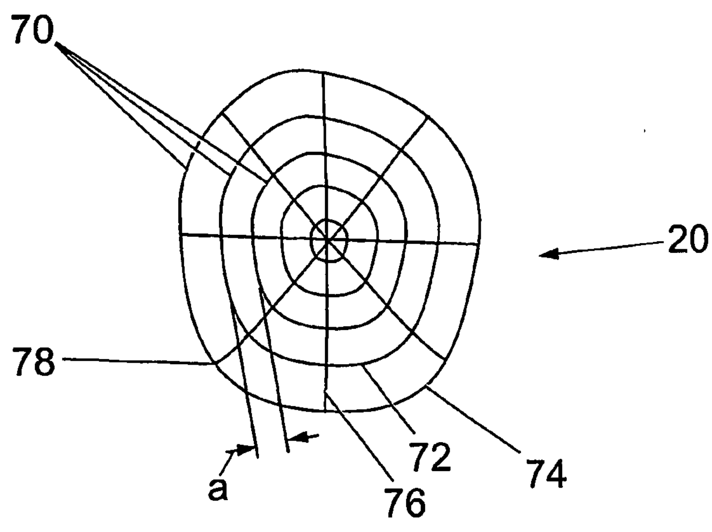


Fig. 9b

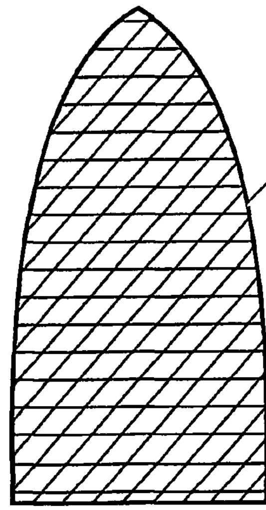


Fig. 9c

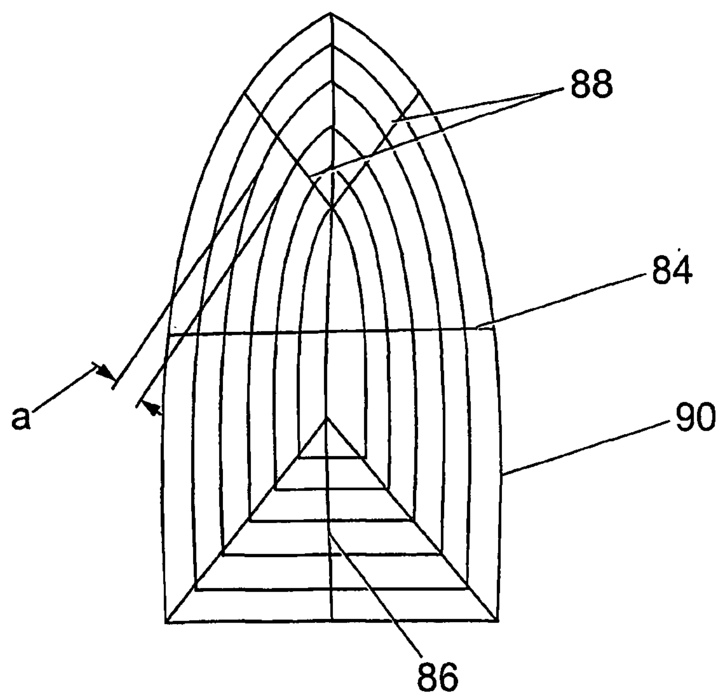


Fig. 9d

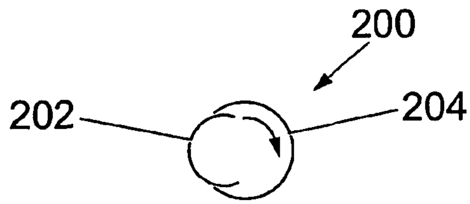


Fig. 10

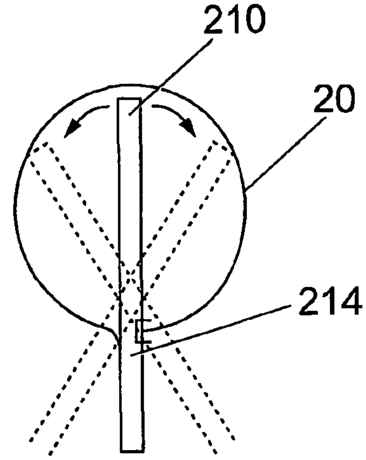


Fig. 11

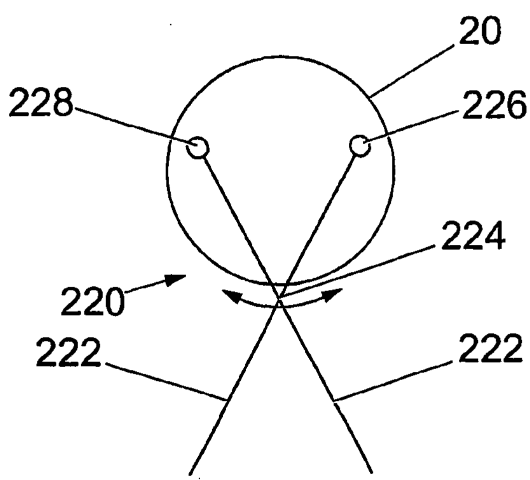


Fig. 12

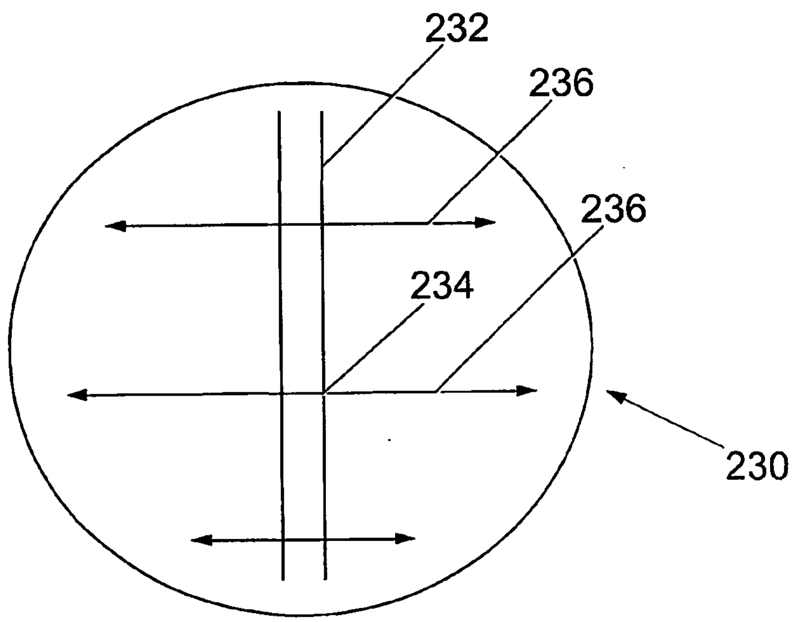


Fig. 13

	International Application No PCT/GB 02/01234

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 732 582 A (SGRO JEAN CLAUDE) 11 October 1996 (1996-10-11)	1,3-8, 16-19, 22,23,64
Y	abstract	15, 20-24, 36, 38-45, 47-53, 57,61-63
	page 4, line 1 -page 5, line 32; table ---	
Y	WO 00 07520 A (PELISSIER EDOUARD) 17 February 2000 (2000-02-17)	15, 38-45, 47-52
A	page 8, line 31 -page 9, line 2; figures --- -/--	3,7,16

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 May 2002	05/06/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	**Authorized officer** Wolf, C

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INTERNATIONAL SEARCH REPORT	International Application No PCT/GB 02/01234

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y A	WO 99 16381 A (SCIMED LIFE SYSTEMS INC) 8 April 1999 (1999-04-08) page 7, line 3 -page 10, line 6	20-24 15,16, 22,23,64
Y A	EP 0 719 527 A (SGRO JEAN CLAUDE) 3 July 1996 (1996-07-03) column 4, line 20 - line 27	21,22 19,20,64
A	US 4 646 731 A (BROWER ARTHUR B) 3 March 1987 (1987-03-03) column 2, line 28 - line 49; figures	28-30
Y A	FR 2 712 177 A (SGRO JEAN CLAUDE) 19 May 1995 (1995-05-19) page 1, line 1 -page 2, line 17; figure	36 1,3-5,7, 8,15-19, 64
Y	WO 98 57590 A (SCIMED LIFE SYSTEMS INC) 23 December 1998 (1998-12-23) page 12, line 7 - line 29	53,57
Y	EP 0 706 778 A (ETHICON INC) 17 April 1996 (1996-04-17) the whole document	61-63
A	WO 96 03091 A (NOTARAS MITCHELL JAMES) 8 February 1996 (1996-02-08) page 3, line 27 -page 5, line 16; figure 1	1,3,5-7, 9,16,18, 19
A	FR 2 735 015 A (MICROVAL) 13 December 1996 (1996-12-13) page 5, line 3 - line 26	36,64
A	EP 0 009 072 A (SIGRI ELEKTROGRAPHIT GMBH) 2 April 1980 (1980-04-02) page 3, line 13 - line 17; figure	3,5-7, 38,40, 42-47

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 02/01234

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
FR 2732582	A	11-10-1996	FR	2732582 A1	11-10-1996
			DE	19613317 A1	10-10-1996
			ES	1033775 U1	16-10-1996
			IT	MI960253 U1	03-10-1997
WO 0007520	A	17-02-2000	WO	0007520 A1	17-02-2000
			AU	8986298 A	28-02-2000
			EP	1100401 A1	23-05-2001
WO 9916381	A	08-04-1999	AU	733858 B2	31-05-2001
			AU	9512598 A	23-04-1999
			CA	2304296 A1	08-04-1999
			EP	1018980 A1	19-07-2000
			JP	2001517534 T	09-10-2001
			WO	9916381 A1	08-04-1999
			US	6197036 B1	06-03-2001
EP 0719527	A	03-07-1996	FR	2728776 A1	05-07-1996
			AT	204723 T	15-09-2001
			DE	69522425 D1	04-10-2001
			DE	69522425 T2	23-05-2002
			EP	0719527 A1	03-07-1996
			ES	2163485 T3	01-02-2002
			US	5697978 A	16-12-1997
US 4646731	A	03-03-1987	NONE		
FR 2712177	A	19-05-1995	FR	2712177 A1	19-05-1995
WO 9857590	A	23-12-1998	US	6213126 B1	10-04-2001
			WO	9857590 A1	23-12-1998
EP 0706778	A	17-04-1996	AU	3315495 A	26-04-1996
			BR	9504376 A	02-09-1997
			CA	2160293 A1	14-04-1996
			CN	1129547 A	28-08-1996
			EP	0706778 A1	17-04-1996
			JP	8206119 A	13-08-1996
			ZA	9508631 A	14-04-1997
WO 9603091	A	08-02-1996	AU	3119495 A	22-02-1996
			WO	9603091 A1	08-02-1996
FR 2735015	A	13-12-1996	FR	2735015 A1	13-12-1996
			WO	9641588 A1	27-12-1996
EP 0009072	A	02-04-1980	DE	2836944 A1	13-03-1980
			EP	0009072 A1	02-04-1980